Research Ethics Board

ROMEO Research Portal User Guide

Nova Scotia Health Authority
Research Ethics Board

Researcher Coordinator's User Manual

Accessing the Researcher's Portal

The Researcher's Portal is available through the Login at the following URL:
http://mreb.researchservicesoffice.com/Romeo.Researcher/Login.aspx

If you are a first time user of the Researcher's Portal, you must click the 'register' button to create an account. Your username should be your primary email address. Once you have registered, you will receive an automatic email with instructions on setting up your password.

Researcher's Home Page

You are now in the Researcher's Home Page! To access the REB application forms, click on "APPLY NEW"

Select the Proper Ethics Application Form (EAF)

nova scotia health authority

APPLY NEW | News | Useful Links | Settings

New Application Forms

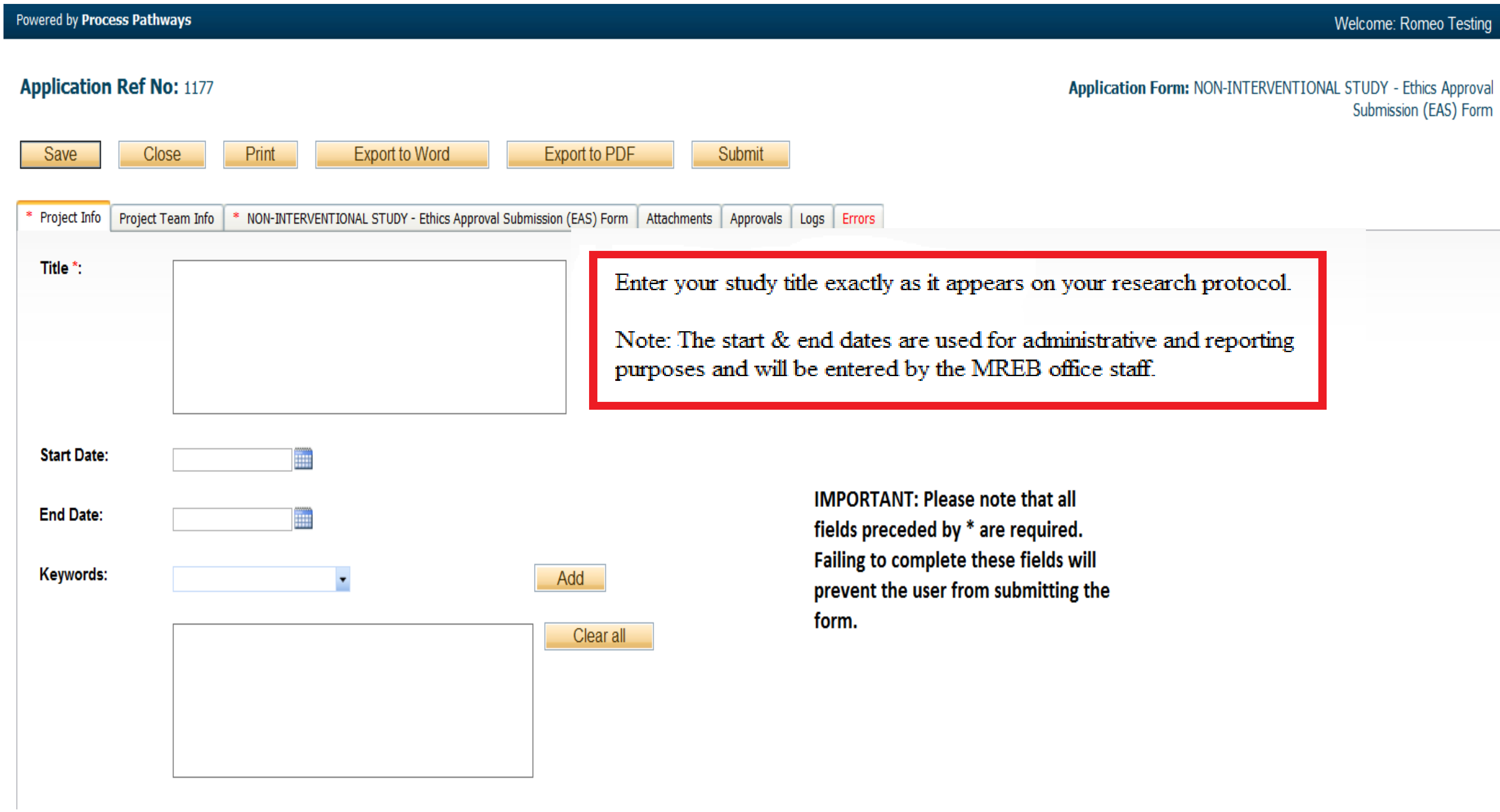
All research projects being conducted in the Nova Scotia Health Authority (NSHA) and involving human participants, human biological materials (human embryos, fetuses, fetal tissue, reproductive materials, stem cells), NSHA patients, staff, resources or data are reviewed by the NSHA REB before the research begins. This applies to materials derived from living and deceased individuals.

Please read the descriptions below and select the appropriate ethics application form for your research submission.

NSHA Ethics Staff

Application Name	Description	Status
INTERVENTIONAL STUDY - Ethics Application Form (EAF)	Interventional Study (or Clinical Trial): A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. — clinicaltrials.gov If your study meets the requirements of an interventional study as per the definition above, complete this form. If your study does not meet the definition of an interventional study, complete the Ethics Application Form for Non-Interventional Studies.	Open
NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)	Complete this form if your study is NOT a clinical trial. If your study is a clinical trial, complete the clinical trials EAF form.	Open

Project Info Tab

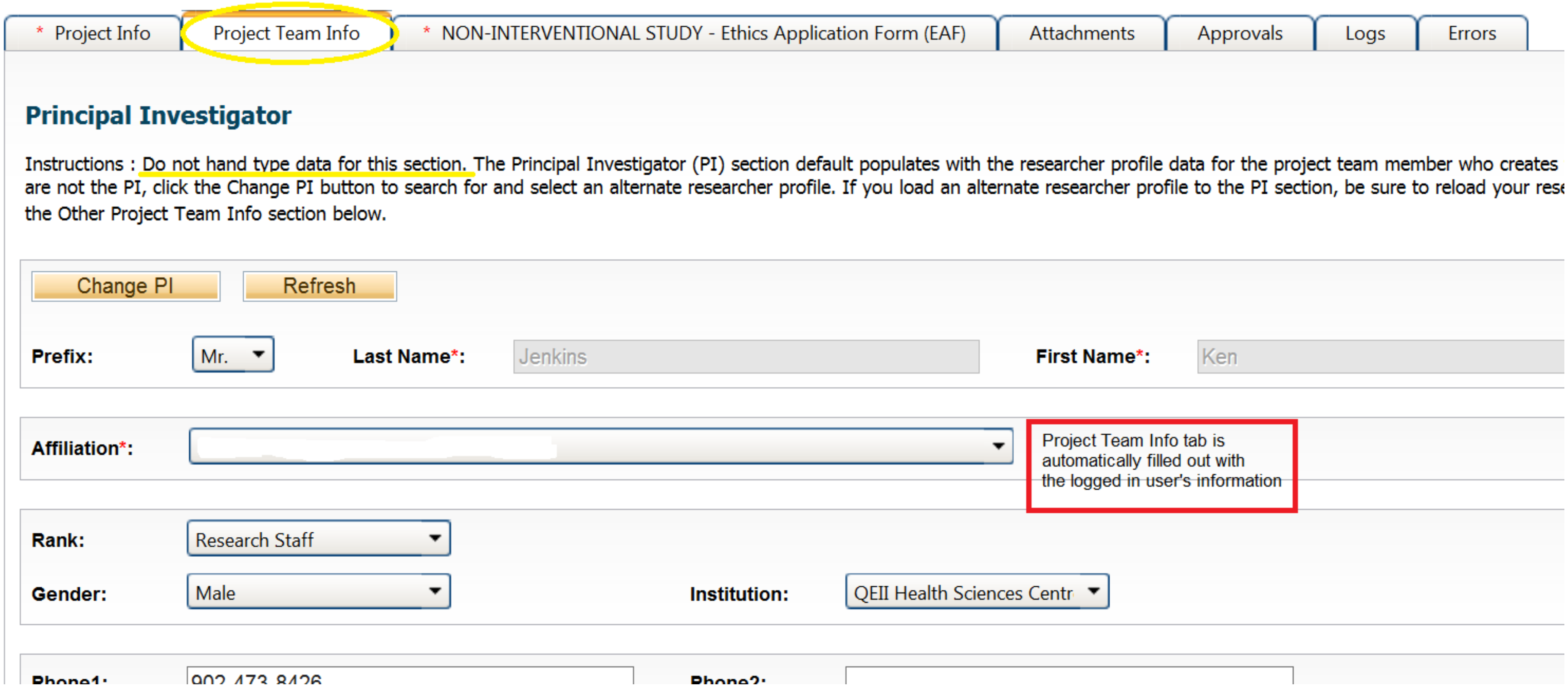


Enter your study title exactly as it appears on your research protocol.

Note: The start & end dates are used for administrative and reporting purposes and will be entered by the MREB office staff.

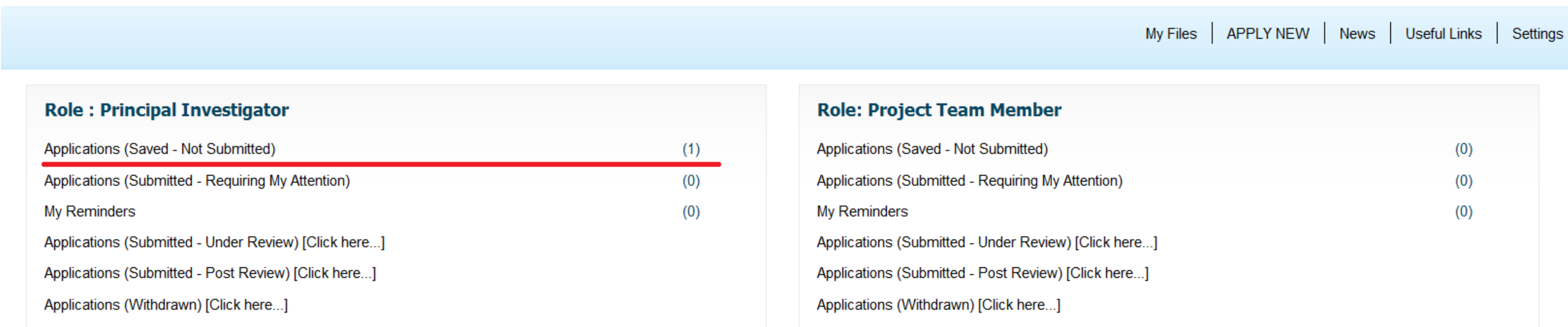
IMPORTANT: Please note that all fields preceded by * are required. Failing to complete these fields will prevent the user from submitting the form.

Project Team Info Tab



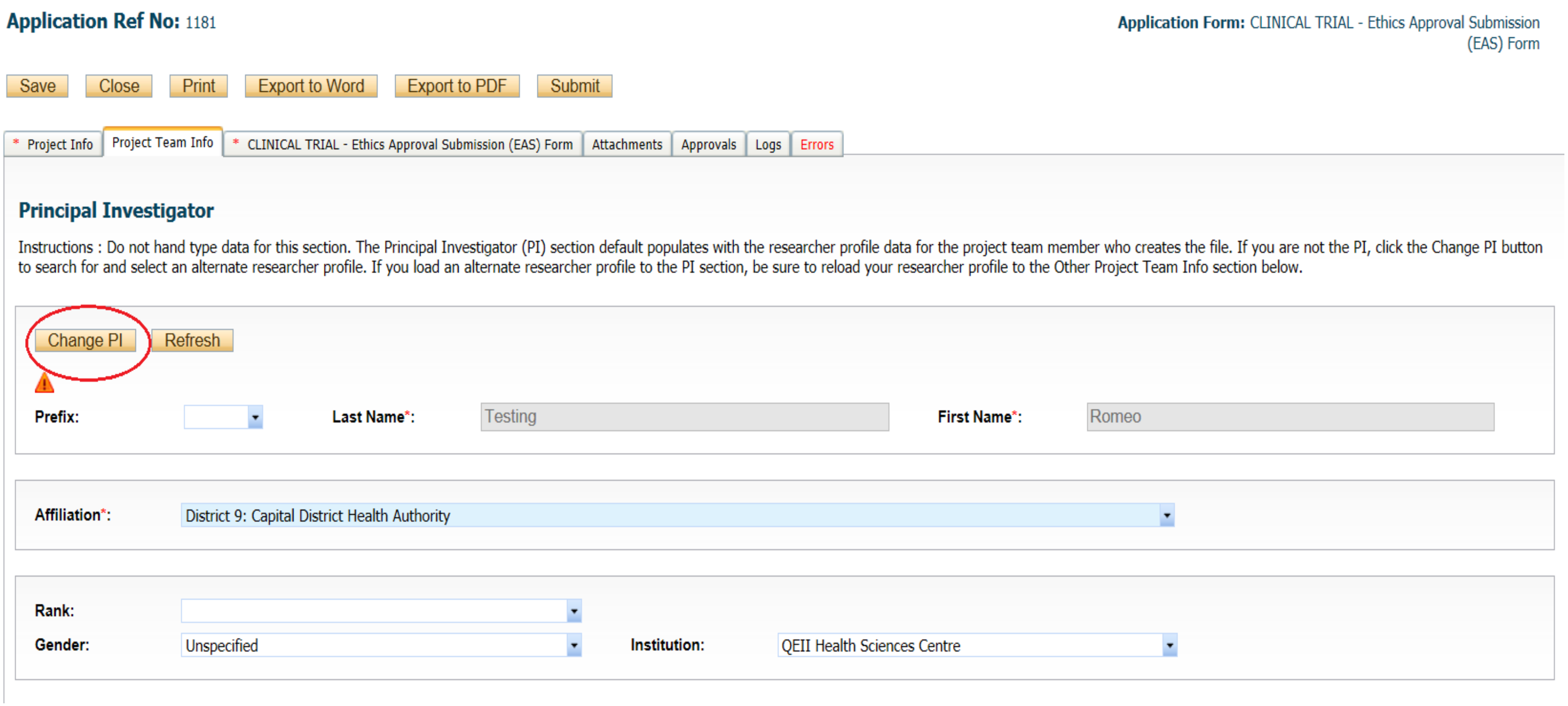
PI Role Versus Project Team Member Role

- At this point, the applicant (person completing application on behalf of the PI) will automatically be designated as PI on the application.
- The role of the applicant from PI to Project Team Member will need to be modified to ensure the application will follow the proper process. This can be done at any point during the completion of the form.
- As long as the applicant remains PI the application will continue to be accessible from the Researcher's home page under "Role: Principal Investigator".



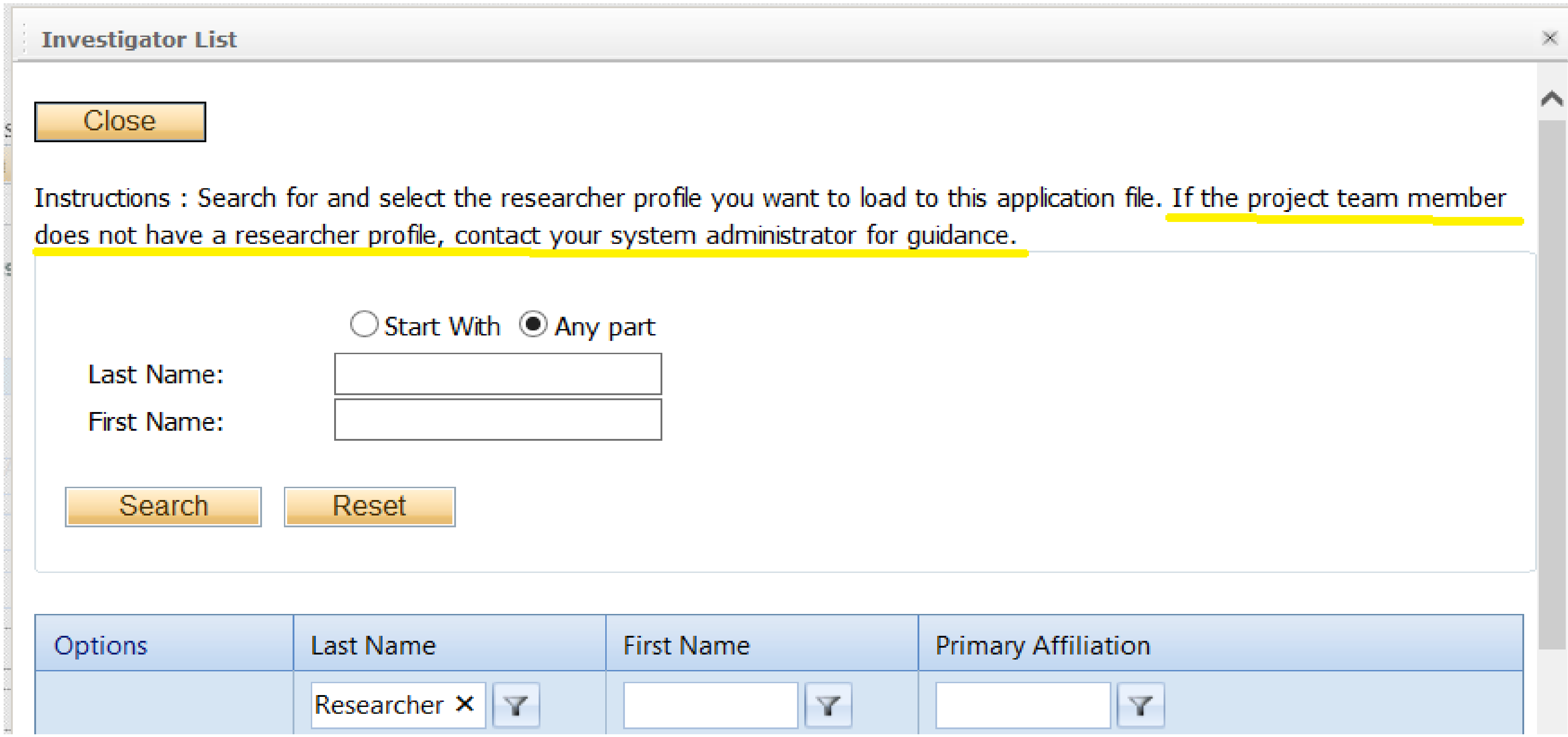
Project Team Info Tab

- Project Team Info tab is automatically filled out with applicant's info. To change the role of PI over to another researcher, click on "Change PI". Important: DO NOT change PI's "Last Name" and "First Name" manually – always use "Change PI" feature.



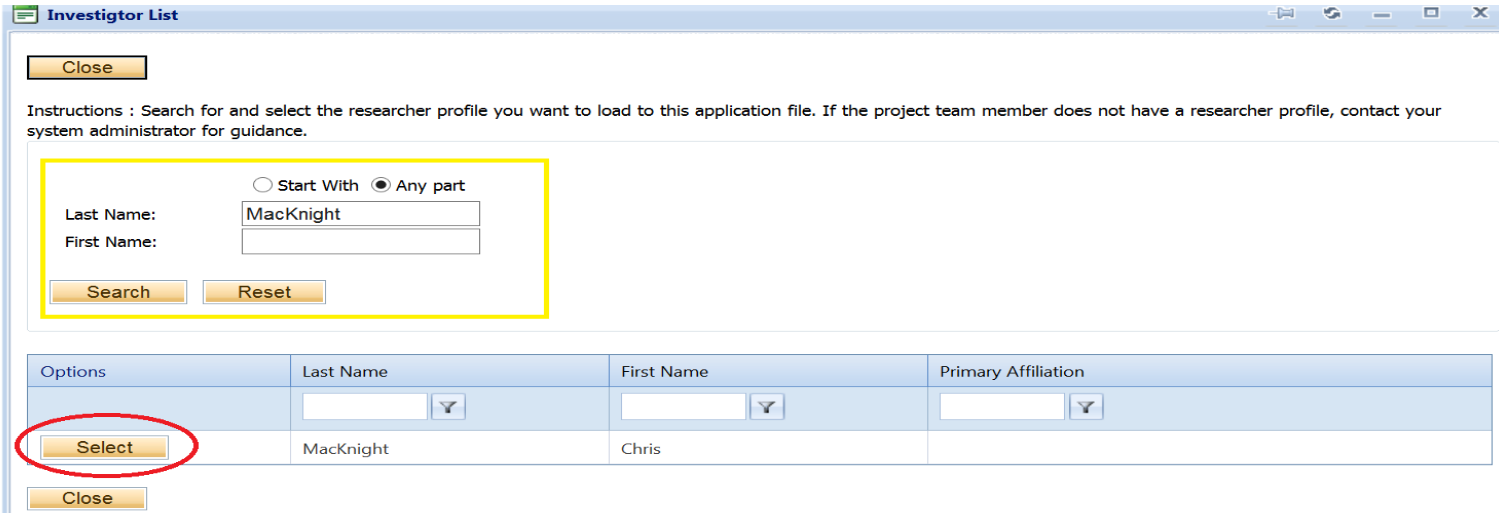
Transferring PI Role to Another Researcher

Once you click “Change PI”, you can search the Investigator List for the name of the person to be assigned as PI. The list can be searched in a variety of ways, i.e. type the last name of the person in the “Last Name” field, or use the filter to select search criteria such as “Start With” or “Any part.”



Transferring PI Role to Another Researcher

- Once you've identified your PI – click on "select".



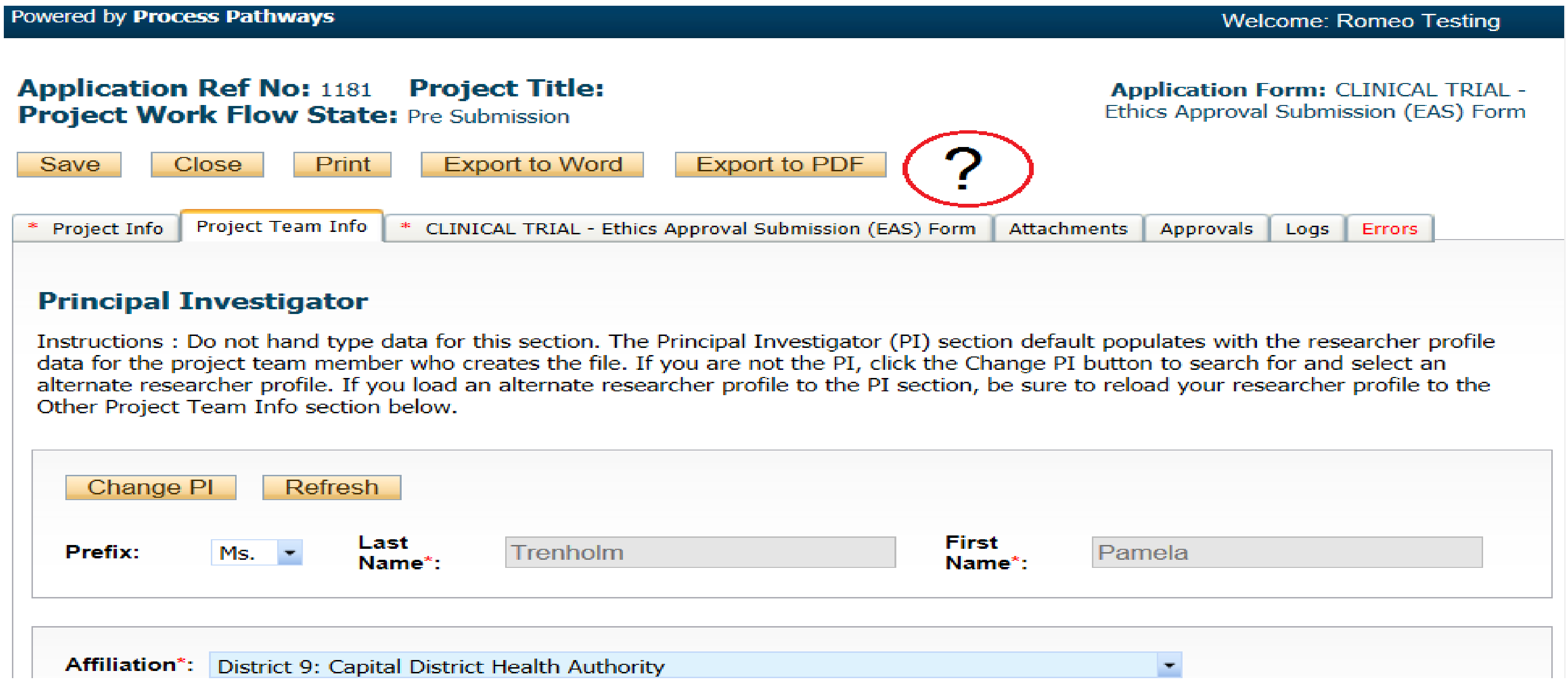
If you are unable to identify the person you are looking for from the investigators list, please email the system administrator (mreb.notifications@nshealth.ca). Your email should include the person's full name, title, business address, office phone number and email address. You will be notified as soon as the person has been added to the investigators list and will then be able to transfer the PI role over to them.

Project Team Info will automatically be updated with PI's information.

Transferring P.I. Role to Another Researcher (cont'd)

At this point, you will also notice that the "Submit" button, previously located at the top of the form, has disappeared.

Important: the next step is to add yourself to the application as a team member. This must be done before you close the application. Failing to do so will result in you losing access to the application form once you exit the application form.



Powered by **Process Pathways** Welcome: Romeo Testing

Application Ref No: 1181 **Project Title:**
Project Work Flow State: Pre Submission

Application Form: CLINICAL TRIAL - Ethics Approval Submission (EAS) Form

Save | Close | Print | Export to Word | Export to PDF | ?

* Project Info | Project Team Info | * CLINICAL TRIAL - Ethics Approval Submission (EAS) Form | Attachments | Approvals | Logs | Errors

Principal Investigator

Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.

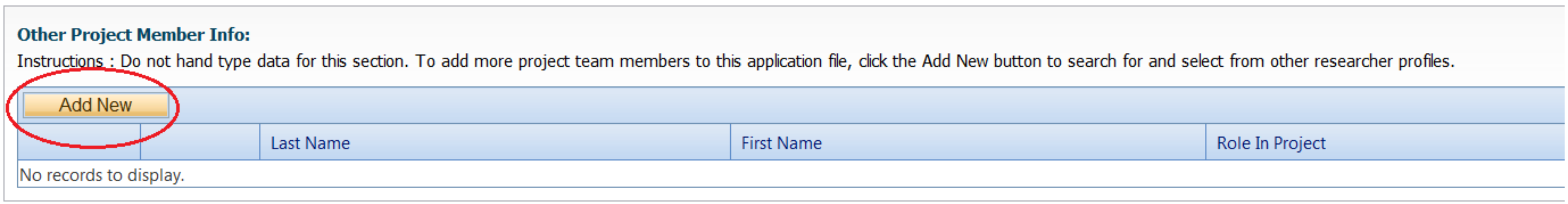
Change PI | Refresh

Prefix: Ms. **Last Name*:** Trenholm **First Name*:** Pamela

Affiliation*: District 9: Capital District Health Authority

Adding Team Members

- From the Project Team Info tab, scroll down to “Other Project Member Info” and click “Add New”
- Repeat the search process, this time assigning yourself to the team and selecting your role in the study from the drop down menu under “Role In Project” data field.
- You may add as many team members as required by clicking “Add New.”



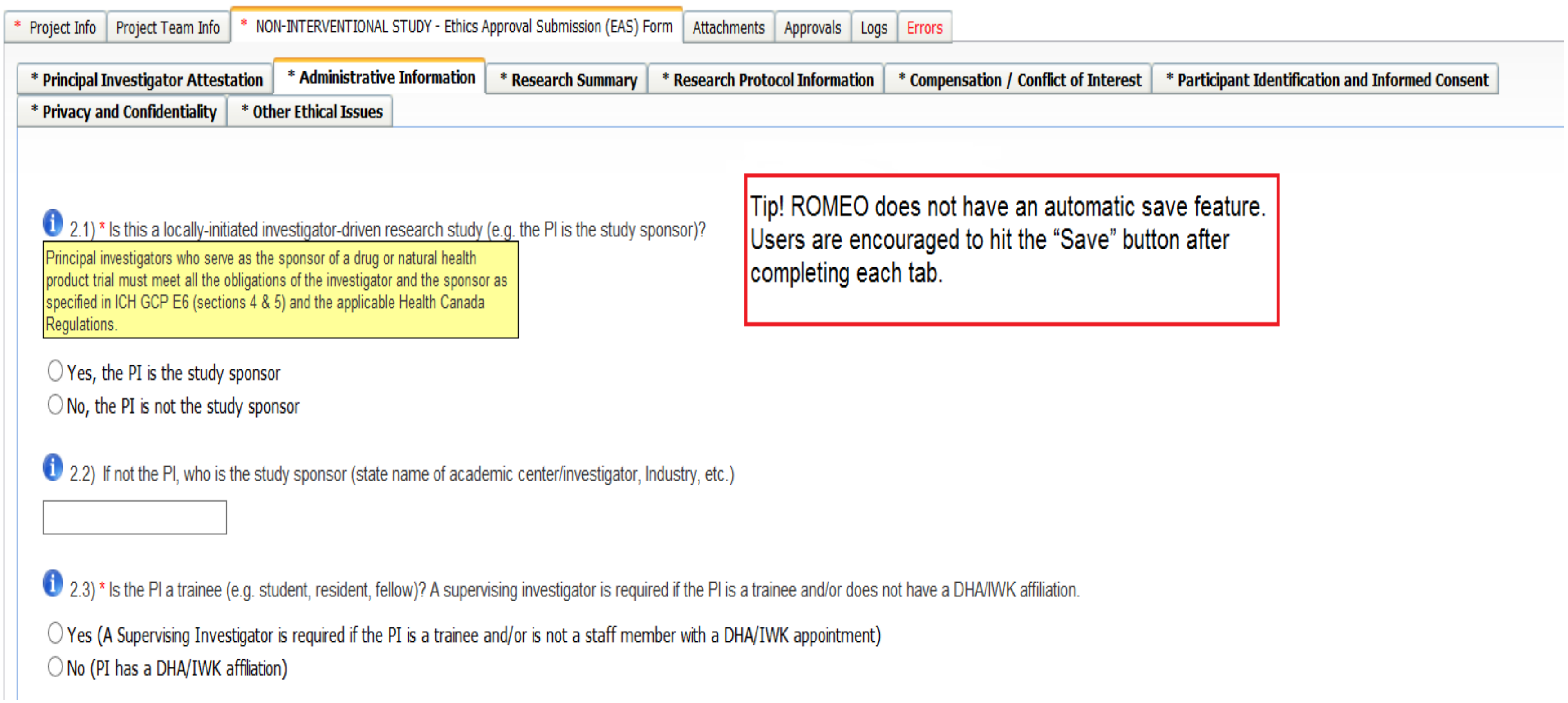
Do not hand type data for this section. Always use “Search Profiles.” If the person you are looking for is not in the list, please contact the system administrator (contact info on last page)

PI Role versus Project Team Member Role

- Once the change has been made on the “Project Team Info” tab, the application will be accessible to the Research Coordinator and to the other team members from the Researcher’s Home Page under “Role: Project Team Member”.
- **Important: The PI is the only person who can submit the application once it has been completed by the Research Coordinator.

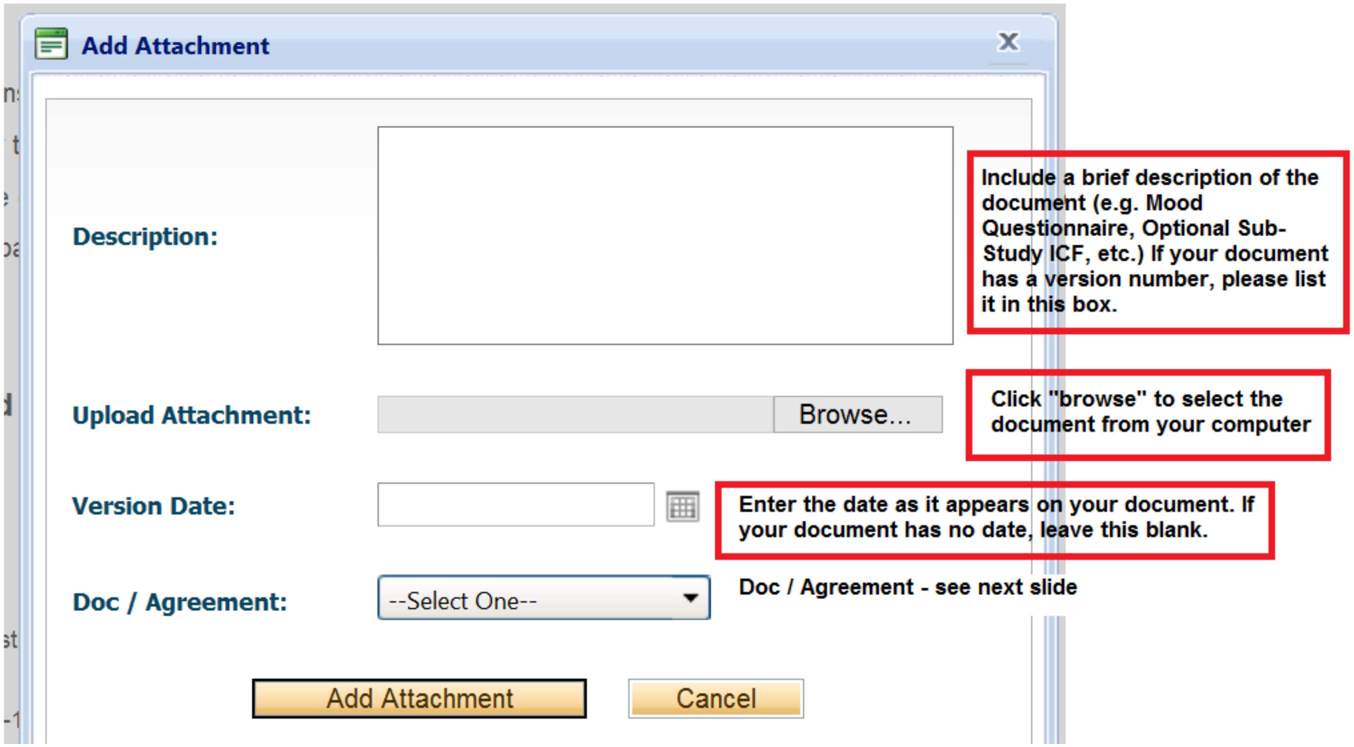
Ethics Application Form (EAF) (Interventional and Non-Interventional Studies)

The Ethics Form(s) have several sub-tabs all of which contain required questions. If you are unsure how to answer a question, try clicking on additional information may be available as seen in the screenshot below!

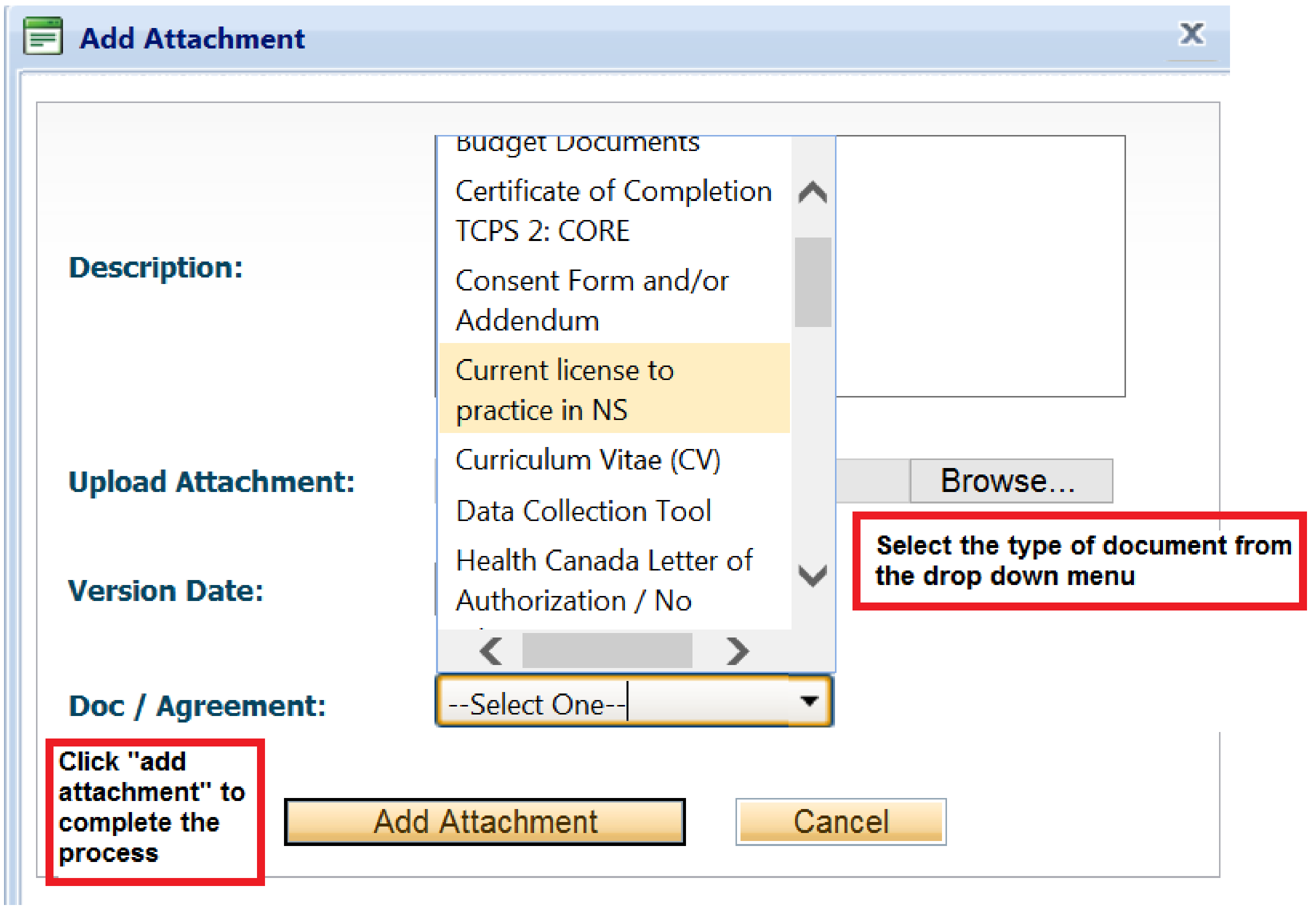


Attachments Tab

You should attach any relevant document(s) as listed on the “Attachments Tab.” Users may upload multiple attachments, provided that each is no larger than 5MB. Attachments may be word files, spreadsheets, jpeg files, pdfs, etc.



Attachments Tab (cont'd)



Errors Tab

* Project Info	Project Team Info	* NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)	Attachments	Approvals	Logs	Errors

The Errors tab keeps a log of any required questions that were left unanswered. If all required questions have been answered, the Errors tab will disappear from view.

Project Info ->Project Title is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.1 Is this a locally-initiated investigator-driven research study (e.g. the PI is the stud
required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.3 Is the PI a trainee (e.g. student, resident, fellow)? A supervising investigator is re
PI is a trainee and/or does not have a DHA/IWK affiliation. is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.4 Has funding been obtained for this study? is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.7 What does this study involve? (select all that apply) is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.8 Has this study been reviewed by a committee, department, or division of a partici
institution? is required.

NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF) -> Administrative Information :2.9 Has this study been reviewed externally (e.g. by funding agencies or other acader
institutions/organizations)? is required.

Save and Continue…

At any point in the process, you may "Save and Close" the application and complete it at a later date. The information entered will be saved and can be accessed again through the Researcher's home page under "Applications (Saved –Not Submitted)". Important: Do not close that application by clicking the X at the top of your browser, doing so will result in the application being "locked" preventing other team members from accessing it.

ROMEO has no automatic save feature! But it does have a time out feature! If you need to step away from your computer, always hit "Save and Close" as a precautionary measure. Failing to do so could result in information being lost or the application being "locked". The user responsible for "locking" the application is able to "unlock" it by accessing it again and exiting properly. All other team members, who find themselves "locked out" of the application, can either contact the user who "locked" it or the system administrator for support (mreb.notifications@nshealth.ca)

Submitting the Application

- From the moment you assign another PI and team members to the project, they will be able to view and edit the application.
- The PI is the only person who can submit the application, no other team member can do this on their behalf.
- The team member responsible for completing the application should notify the PI when the application is ready to be reviewed and submitted.
- Once the application has been submitted, the PI will receive an email confirming the receipt of the application – any team member associated with the application will be copied on the correspondence.

Applications Under Review

Once the PI has submitted the application for review, you will receive an email confirming the receipt of the application – any team member associated with the application will be copied on the correspondence. At this stage, you will not be allowed to make any changes to the application. However, it is still available for viewing under "Applications (Submitted – Under Review)".

Work Flow State of Applications Under Review

Check the status of your application(s) under review under the "Work Flow State" column.

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot	Workflow Message
				All		
View Clone	**100239**	Test File	Romeo Testing (District 9: Capital District Health Authority)	CLINICAL TRIAL - Ethics Approval Submission (EAS) Form (Certification\Human Ethics)	**Project Status:** Active **Workflow Status:** ORS Review	Test application being submitted for review [Acti... [See more, inside under Logs section]

Applications Requiring Revisions

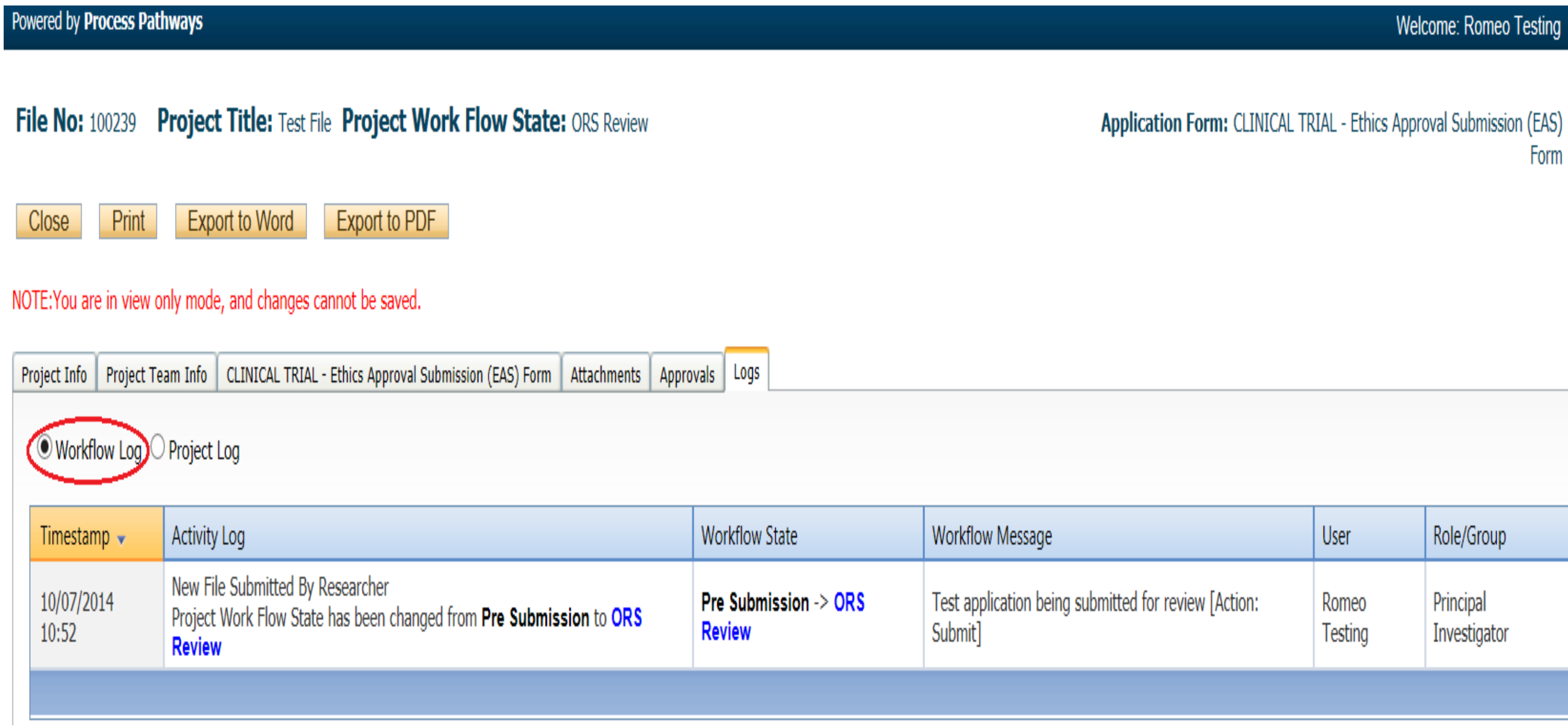
If the Board requires any revisions, the application will be pushed back to the researcher (applicant/PI). At this stage, you will be able to edit the application by clicking on this link: “Applications (Submitted – Requiring my Attention)”. Remember that if you are making the revisions on behalf of the PI, you will need to let them know when the revisions are completed so that they may re-submit the application.

Approved Applications

Once the application has been approved, the PI, Research Coordinator and Supervising Investigator (where applicable) will receive an automatic email the study has been approved. A formal approval letter in the form of email will also be sent. The application can no longer be modified but is available for viewing under "Applications (Submitted – Post Review)"

Logs Tab – Workflow Logs

- The Logs tab is a useful tool that shows the history of the application. Text in blue font represents most recent updates
- The "Workflow Logs" tracks and time stamps approvals and messages



Logs Tab – Project Logs

- The "Project Logs" tracks and time stamps every action taken on the application.

File No: 100239 **Project Title:** Test File **Project Work Flow State:** ORS Review

Application Form: CLINICAL TRIAL - Ethics Approval Submission (EAS) Form

Close | Print | Export to Word | Export to PDF

NOTE:You are in view only mode, and changes cannot be saved.

Project Info | Project Team Info | CLINICAL TRIAL - Ethics Approval Submission (EAS) Form | Attachments | Approvals | Logs

○ Workflow Log ◉ Project Log

Timestamp	Log Activity	User
2014/07/10 11:09	Project Status has been changed from to **Active**	
2014/07/10 10:52	Project Work Flow State has been changed from **Pre Submission** to **ORS Review**	Romeo Testing
2014/07/10 10:45	**CLINICAL TRIAL - Ethics Approval Submission (EAS) Form :** Other Ethical Issues -> Are you aware of any other ethical issues regarding the design or conduct of the study? has been changed from **''** to **'No'**	Romeo Testing
	CLINICAL TRIAL - Ethics Approval Submission (EAS) Form : Privacy and Confidentiality -> Will researchers' personal information be transferred to parties who may store or access the information outside Canada? has been changed from **''** to **'No'** Privacy and Confidentiality -> Describe administrative, physical and technical measures to be taken to safeguard the personal health information and study data. has been changed from **''** to **'/'** Privacy and Confidentiality -> Will any personal health information (PHI) be collected or used to conduct the research or identify potential participants? (See description for definition) has been changed	

Event Forms

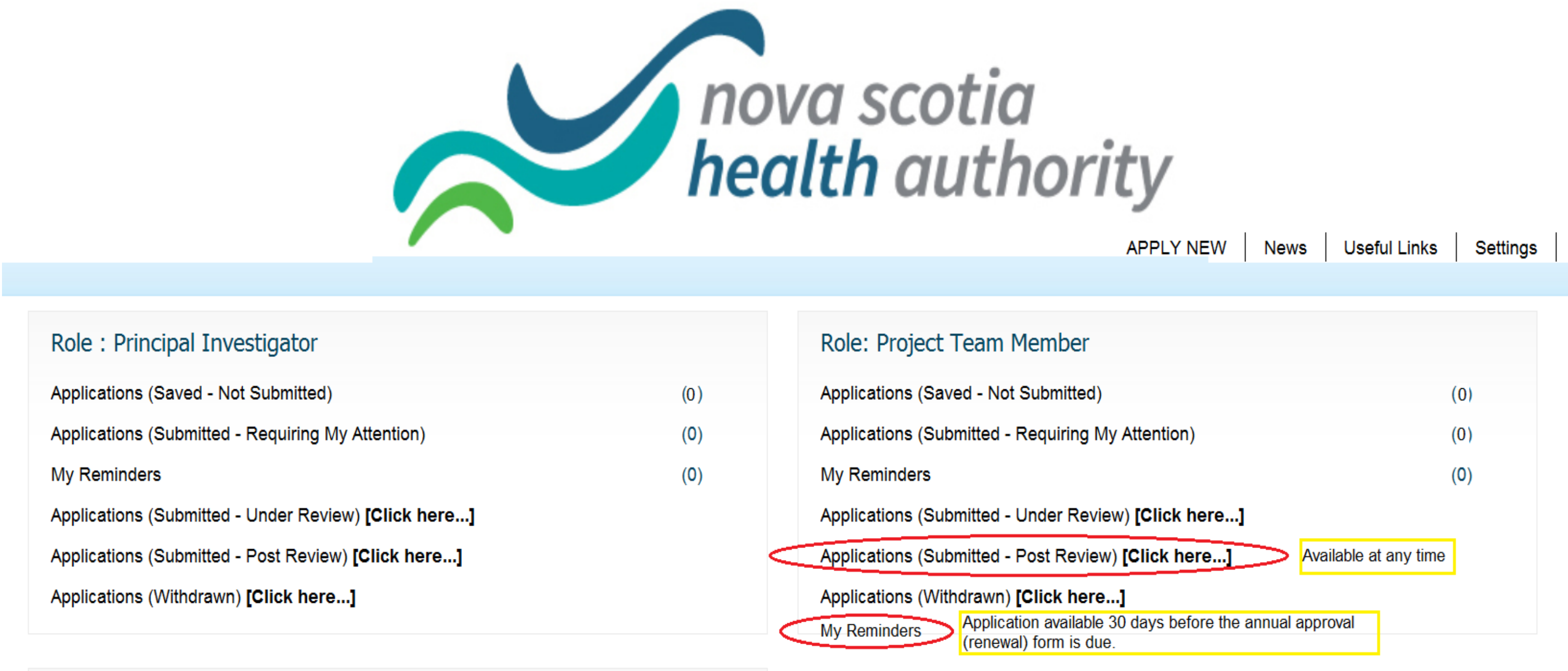
- Event forms are: Amendments, Requests for Annual Approvals, Request for Acknowledgment, Serious Adverse Event (SAE) Reporting, Safety Updates and Study Completion.

- "Event Forms" allow researchers to make amendments to their approved ethics application(s).

- Event Forms can be accessed, completed and submitted by any member of the project team (i.e. the PI, Sub-investigator(s), Research Coordinator, etc.) as opposed to the original ethics application which can only be submitted and re-submitted by the PI.

Accessing Event Forms

- You can access Event Forms at any time either under Role: Project Team Member by clicking on “Applications (Submitted – Post Review)”.
- Applications will also be available within 30 days of the ethics renewal due date by clicking on “My Reminders”.



Accessing Event Forms – Applications (Submitted – Post Review)

- By clicking on “Applications (Submitted – Post Review)”, you may view all of your approved ethics applications. From there, if you wish to submit an amendment form, a serious adverse event (SAE) or an annual approval (renewal) request, you can access the event forms by clicking on “Events”.

My Files | APPLY NEW | News | Useful Links | Settings

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot	Workflow Message
				All		
View Edit Events	**Ref No :1184**		Romeo Testing (District 9: Capital District Health Authority)	CLINICAL TRIAL - Ethics Approval Submission (EAS) Form (Certification\Human Ethics)	**Project Status**: Pending **Workflow Status**: Pre Submission **Last Saved**: 2014/07/14	

Accessing Event Forms

APPLY NEW | News | Useful Links | Settings |

File No: 6007658

Title: Test-January 17, 2013

New Event Forms

- Study Closure
- Request for Annual Renewal
- Request for Amendment
- Request for Acknowledgement
- Safety related events reporting (PSUR, DSMB, Safet ...
- Major Study Violation
- Local Serious Unexpected Adverse Reaction Reportin ...

Select the form you need to submit by clicking on the hyperlinks under "New Event Forms".

My Reminders

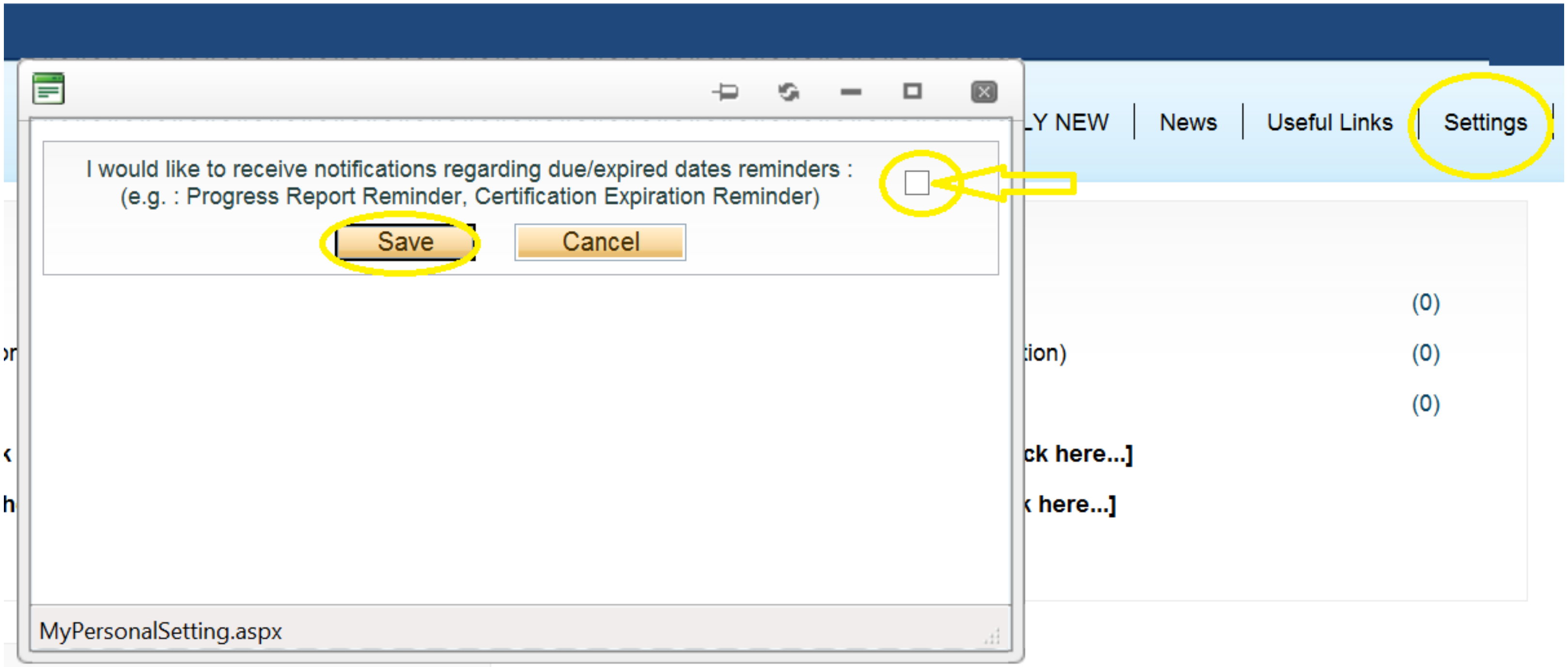
My Expired Reminders

My Events

	Form	Category	Status	SubmissionDate
View Event		New Approval Process	Active	2013/01/4

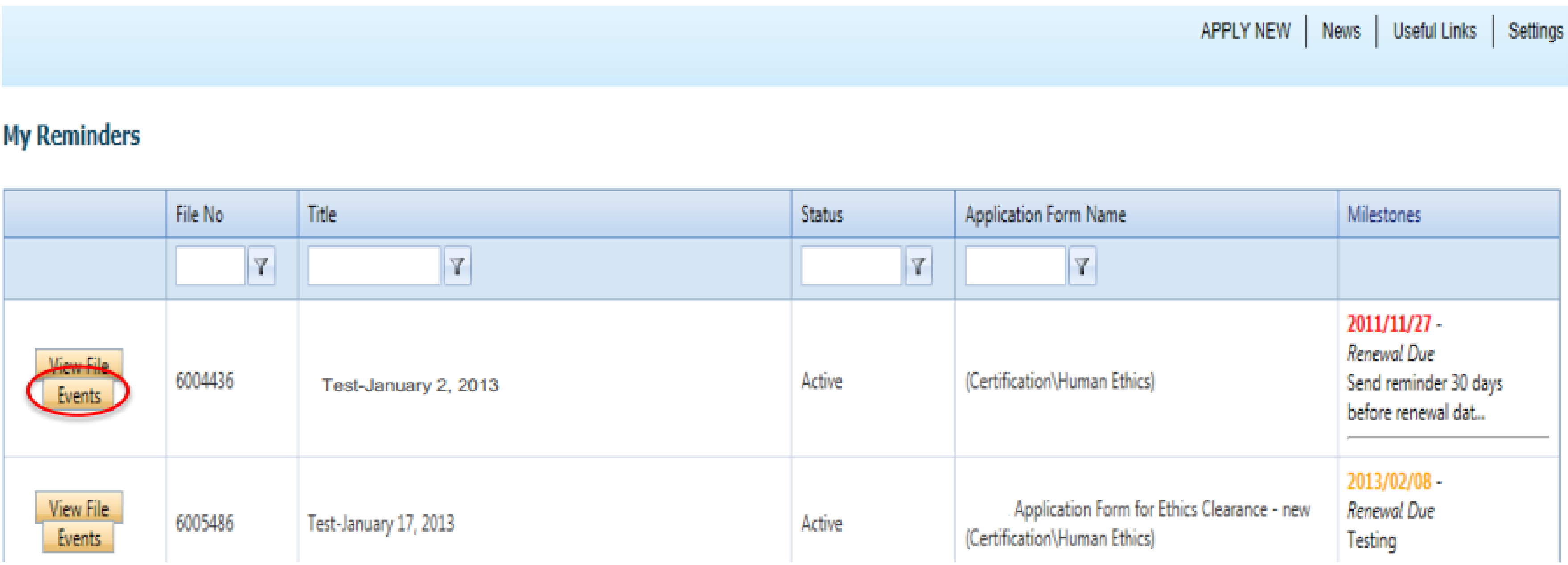
Setting Reminders

- To receive reminders (e.g. annual approval due in 30 days), click on “Settings.” Tick the box to receive reminders and then click “save.”

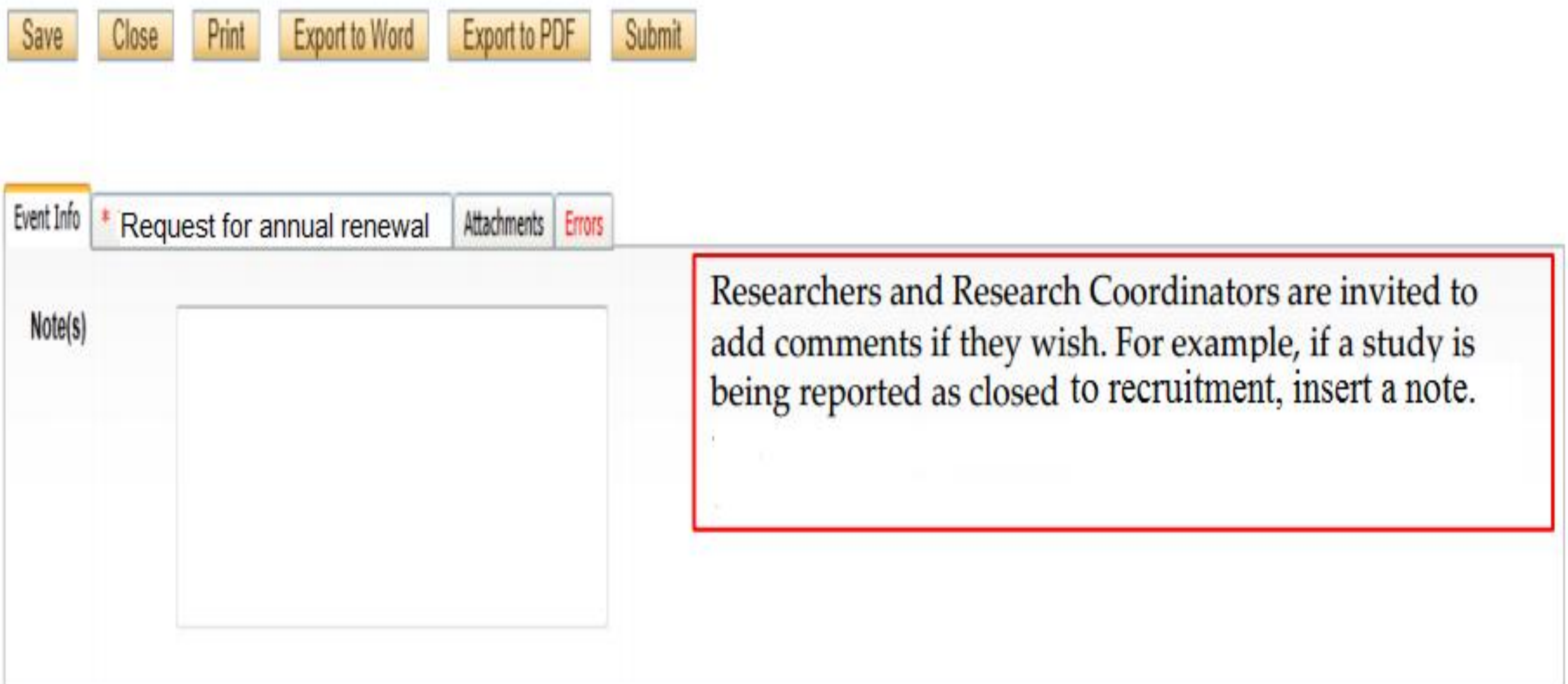


Accessing Event Forms – My Reminders

- From the “My Reminders” quick link you will see the due date of the “Milestones” –dates in yellow font are coming due, while dates in red font are past due. Click on “Events” to access the forms.

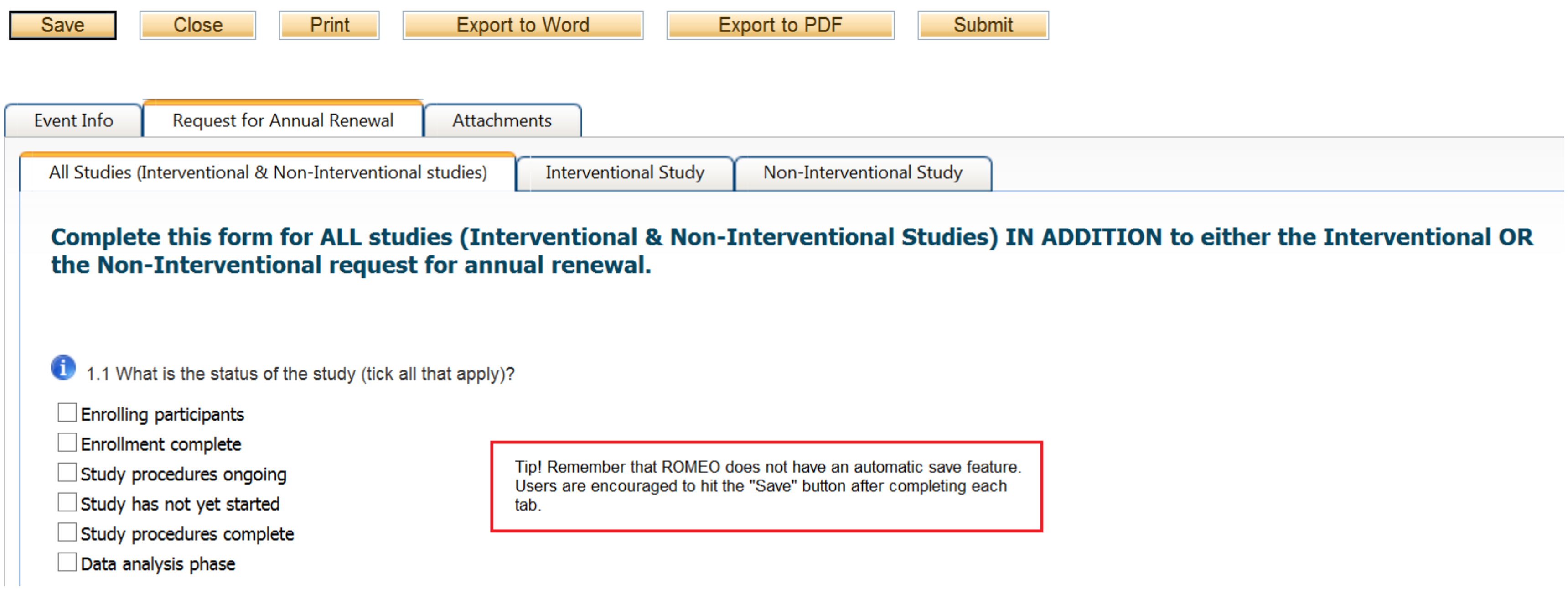


Event Info Tab



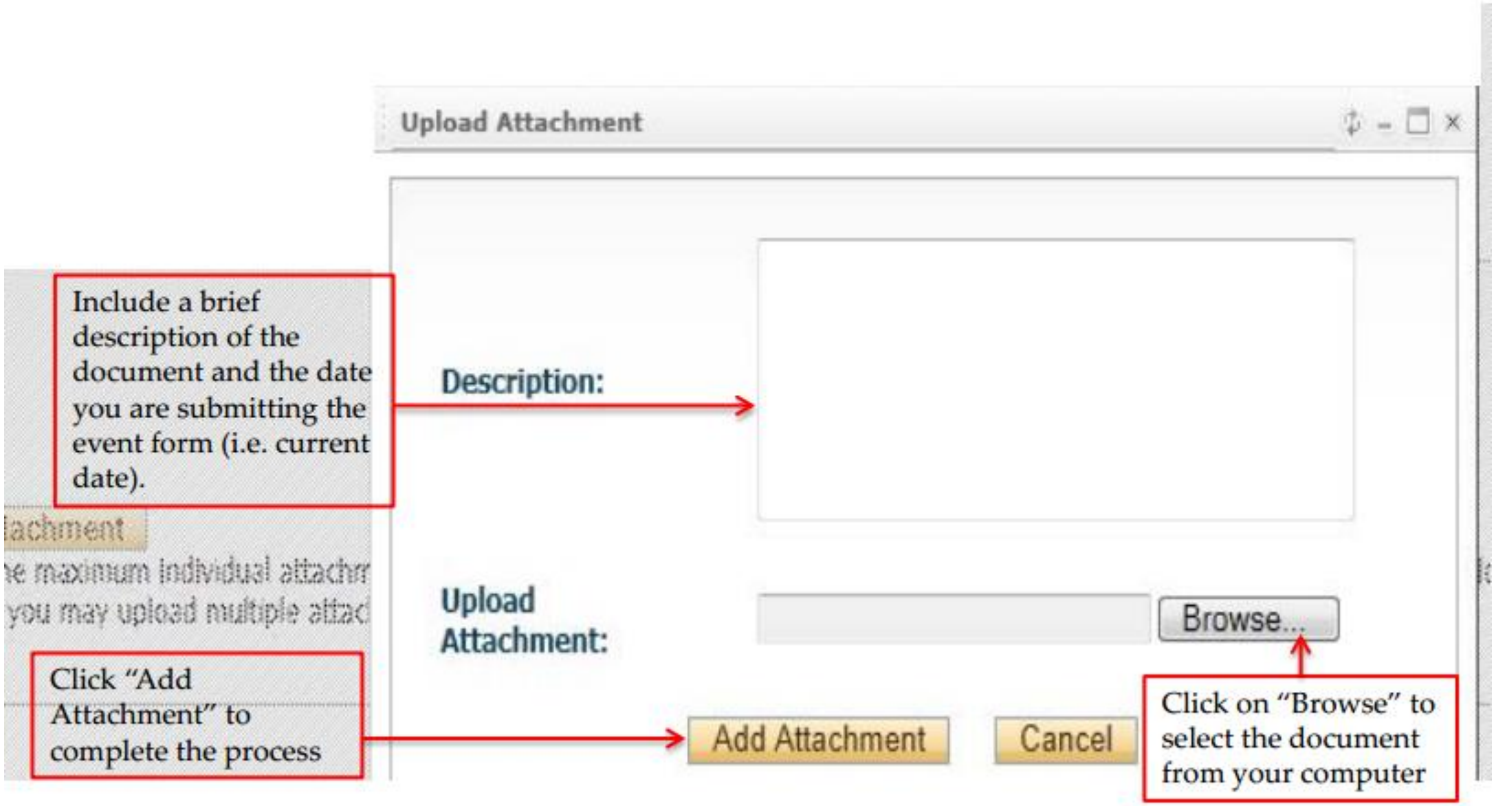
Completing the Event Form

- Complete the form by answering all the questions of the Annual Renewal Form for All Studies (Interventional and Non-Interventional Studies). Once all of these questions have been answered, click on either the Interventional or Non-Interventional Studies sub-tab (as it applies to your study) and answer the remaining questions.



Attachments Tab

- Researchers are able to attach document(s) to the event form through the Attachments tab. Users may upload multiple attachments, provided that each is no larger than 5MB. Attachments may be Word documents, Excel spreadsheets, jpeg files, pdfs, etc.



Errors Tab

Request for Amendment

Save | Close | Print | Export to Word | Export to PDF | Submit

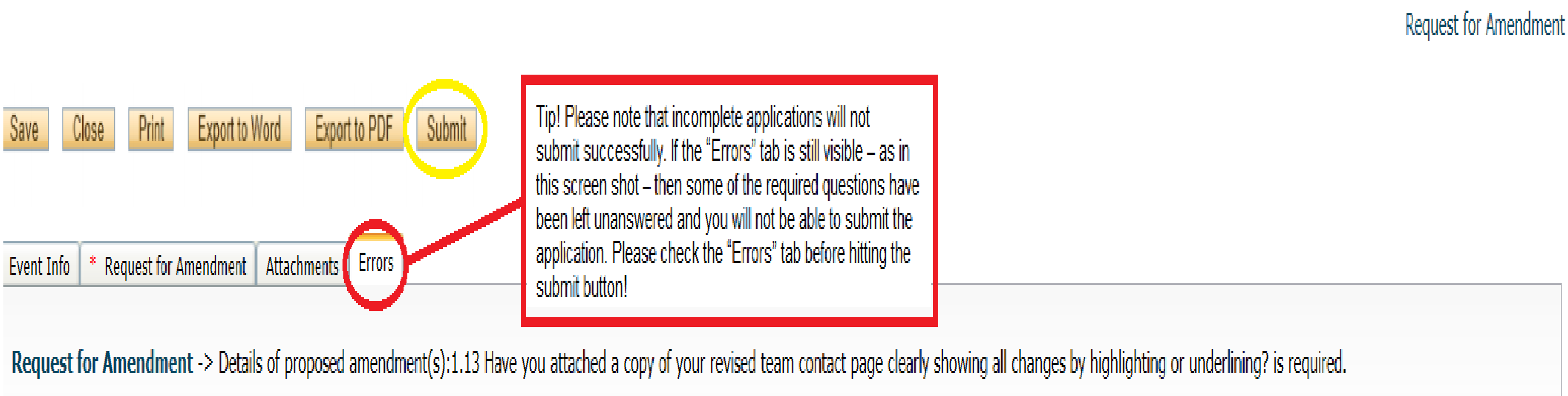
Event Info | * Request for Amendment | Attachments | Errors

Request for Amendment -> Details of proposed amendment(s):1.13 Have you attached a copy of your revised team contact page clearly showing all changes by highlighting or underlining? is required.

The Errors tab keeps a log of any required questions that were left unanswered. If all required questions were answered, the Errors tab disappears.

Submitting the Event Form

- Remember that any member of the project team (i.e. PI, Sub-Investigator, Research Coordinator, etc.) is able to submit event forms by simply clicking the "Submit" button at the top of the form.



Tracking the Event Form

- The PI and other members of the project team will not receive a confirmation email after submitting an event form.
- However, they can still track whether or not their form was submitted by accessing the application for which you submitted an event form – either through "Applications (Submitted – Post Review)" or "My Reminders" – and clicking on "Events". Event forms that were started and saved, but not submitted will appear under "My Saved Events".

My Reminders

Milestone	Due Date	Comments	Sponsor	Event	Related Forms
Renewal Due	2013/02/8		N/A	Renewal	Annual Renewal Form

My Expired Reminders

Tip! As long as the event form has not been submitted, you will be able to edit it. If you can see the "Edit Event" button, you have not submitted the form yet!

My Saved Events

		Ref#	Comments	Category	Form
Delete	Edit Event	32	Submitted on behalf of Researc ...	Renewal	HSREB Annual Renewal Form for Approved Studies

Tracking the Event Form (cont'd)

- Once the event form has been submitted, it will move down to "My Events". You will be able to view the event but will no longer be able to edit it.

My Reminders

Milestone	Due Date	Comments	Sponsor	Event	Related Forms
Renewal Due	2013/02/8		N/A	Renewal	Annual Renewal Form

My Expired Reminders

Note that the "Status" of the application indicates: "Submitted by Researcher".

My Events

	Form	Category	Status	SubmissionDate
View Event	Annual Renewal Form	Renewal	Submitted by Researcher	2013/01/25

Tracking the Event Form (cont'd)

- Once the event form has been assigned for review the "Status" of the application will change from "Submitted by Researcher " to "Pending".

My Reminders

Milestone	Due Date	Comments	Sponsor	Event	Related Forms
Renewal Due	2013/02/8		N/A	Renewal	Annual Renewal Form

My Expired Reminders

My Events

	Form	Category	Status	SubmissionDate
View Event	Annual Renewal Form	Renewal	Pending	2013/01/25

Event Form Approval

- Once the event form has been reviewed and approved, the status of the event will change from “Pending” to “Active”.
- The PI , Research Coordinator and the Supervising Investigator (if applicable) will receive a confirmation email along with a copy of the formal approval letter. This letter has also been attached to the original application and can be viewed through the “Attachments” tab by any project team member.
- Please Note: The process for submitting any type of Event Form is the same as what has been described here.

My Events

	Form	Category	Status	SubmissionDate
View Event	Annual Renewal Form	Renewal	Active	2013/01/22

Need assistance/have a question?

- Contact your system administrator
  - 902-473-2126
  - mreb.notifications@nshealth.ca